



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA-2021-N-0471]

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water; Proposed Rule; Public Meetings; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meetings; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing two virtual public meetings entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water.” The purpose of the public meetings is to discuss the proposed rule entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water,” which was issued under the FDA Food Safety Modernization Act (FSMA). These public meetings are intended to facilitate and support the public’s evaluation and commenting process on the proposed rule.

DATES: The public meetings will be held virtually on February 14, 2022, from 11:45 a.m. Eastern Time to 7:45 p.m. Eastern Time and February 25, 2022, from 8:45 a.m. Eastern Time to 4:45 p.m. Eastern Time. Submit either electronic or written comments on the proposed rule “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water” by April 5, 2022. See “How to Participate in the Public Meetings” in the SUPPLEMENTARY INFORMATION section of this document for closing dates for advanced registration and other information regarding meeting participation.

ADDRESSES: Due to the impact of the COVID-19 pandemic, these meetings will be held virtually to help protect the public and limit the spread of the virus.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 5, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 5, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2021-N-0471 for the proposed rule “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469,

September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: For general questions about the public meetings or for special accommodations due to a disability, contact Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1731, Juanita.Yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Congress enacted FSMA (Pub. L. 111-353) in 2011 in response to dramatic changes in the global food system and in our understanding of foodborne illness. FSMA transformed the nation’s food safety system by shifting the focus from responding to foodborne illness to preventing it.

In November 2015, FDA issued the “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” rule (80 FR 74354, November 27, 2015) (2015 produce safety final rule) (codified at part 112 (21 CFR part 112)), which established science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. The provisions of the rule focus on addressing major routes of microbial contamination—including agricultural water; biological soil amendments; domesticated and wild animals; worker health and hygiene; and equipment, buildings, and tools.

Part 112, subpart E in the 2015 produce safety final rule, which outlines standards for agricultural water, includes a general requirement that agricultural water must be safe and adequate for its intended uses (§ 112.41). It also includes microbial water quality criteria (§ 112.44) and requirements for testing certain water sources (§ 112.46). The microbial quality criteria are based on the intended use of the agricultural water, such as for growing activities for covered produce other than sprouts (including irrigation water applied using direct water application methods and water used in preparing crop sprays) (commonly referred to as “pre-harvest agricultural water”),¹ and for certain other specified uses, including sprout irrigation water and water applications that directly contact covered produce during or after harvest.² Since finalizing the rule, however, we have received consistent feedback from stakeholders expressing concern about the complexity of and implementation challenges with certain agricultural water requirements.

Accordingly, in the *Federal Register* of December 6, 2021 (86 FR 69120), FDA published the proposed rule entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water” (2021 agricultural water proposed rule). This proposed rule would amend the agricultural water provisions of the produce safety regulation to replace the microbial criteria and testing requirements for pre-harvest agricultural water for covered produce (other than sprouts) that covered farms have found to be complex and challenging to implement, with provisions for comprehensive assessments of pre-harvest agricultural water systems, practices, and on-farm conditions.

The proposed agricultural water assessments would provide additional flexibility to covered farms, using a systems-based approach that would be feasible to implement across the wide variety of pre-harvest agricultural water systems, uses, and farm operations and would be adaptable as scientific understanding of agricultural water quality expands in the future. We also

¹ The produce safety regulation refers to pre-harvest agricultural water used during sprout production as “sprout irrigation water.”

² Because sprouts present a unique safety risk, the produce safety regulation establishes sprout-specific requirements on multiple topics, including agricultural water.

are proposing to require expedited mitigation for hazards related to certain activities associated with adjacent and nearby land in light of findings from several recent produce outbreak investigations.

These proposed revisions to the produce safety regulation, if finalized, would set forth requirements for comprehensive pre-harvest agricultural water assessments and mitigation measures that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce, and to provide reasonable assurances that the produce is not adulterated on account of these hazards.

FDA is announcing two virtual public meetings entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water” so that stakeholders can better understand, evaluate, and comment on the proposed rule. These meetings will be held during the formal comment period on the proposed rule. The two public meetings will cover the same agenda items and are intended to facilitate and support the public’s evaluation and commenting process.

II. Purpose and Format of the Public Meetings

The purpose of the public meetings is to provide information and facilitate public comment on the proposed rule. We invite interested parties to provide information and offer comments related to the proposed rule. During the public meetings we will provide an overview of the current requirements that apply for pre-harvest agricultural water for non-sprout covered produce and discuss the proposed provisions for systems-based pre-harvest agricultural water assessments that are designed to be more feasible to implement across the wide variety of agricultural water systems, uses, and practices, while also being adaptable to future advancements in agricultural water quality science and achieving improved public health protections. There will be an opportunity for questions, as well as an opportunity for open public comment.

III. How to Participate in the Public Meetings

There will be a total of two virtual public meetings with different timeframes, which will provide persons in different regions an opportunity to comment on the proposed rule.

Table 1 provides information on participation in the public meetings.

Table 1.--Information on Participating in the Public Meetings and on Submitting Comments to the Proposed Rule Docket

Activity	Date	Electronic Address	Other Information
First public meeting	February 14, 2022; 11:45 a.m. to 7:45 p.m. EST	Webcast information will be sent upon completion of registration.	Webcast will have closed captioning.
Request to make an oral presentation	By February 2, 2022	https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements	---
Notice confirming opportunity to make an oral presentation	By February 4, 2022	---	An Agency representative will confirm the opportunity to make an oral presentation and will provide the approximate time on the public meeting agenda to do so.
Second public meeting	February 25, 2022; 8:45 a.m. to 4:45 p.m. EST	Webcast information will be sent upon completion of registration.	Webcast will have closed captioning.
Request to make an oral presentation	By February 11, 2022	https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements	---
Notice confirming opportunity to make an oral presentation	By February 15, 2022	---	An Agency representative will confirm the opportunity to make an oral presentation and will provide the approximate time on the public meeting agenda to do so.
Submitting either electronic or written comments	Submit comments by April 5, 2022.	https://www.regulations.gov	See ADDRESSES for additional information on submitting comments.

IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at:
<https://www.regulations.gov>. You may also view the transcript at the Dockets Management
Staff (see ADDRESSES).

Dated: December 29, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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